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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/700,057 | 02/05/2001 | Colin Brown | 9052-67 | 1282 |
| 20792 | 7590 | 06/02/2004 | EXAMINER | |
| MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | WHITE, EVERETT NMN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |
| DATE MAILED: 06/02/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,057

Applicant(s)

BROWN, COLIN

Examiner

EVERETT WHITE

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,14-18,21-24,26-35 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,14-18,21-24,26-35 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9/19/03.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 12, 2004 has been entered.

2. The amendment filed February 12, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Claims 3, 11-13, 19, 20, 25, and 36-38 have been canceled;
- (B) Claims 1, 22, 23 and 39-43 have been amended;
- (C) Comments regarding Office Action have been provided drawn to:
 - (a) 112, 2nd paragraph rejection, which has been withdrawn;
 - (b) 112, 1st paragraph rejection, which has been withdrawn;
 - (c) 103(a) rejection, which has been maintained for the reasons of record.

3. Claims 1, 2, 4-10, 14-18, 21-24, 26-35, and 39-43 are pending in the case.

4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd Paragraph

5. Claims 1, 2, 4-10, 14-18, 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants are reminded that a difference in intended use cannot render a claimed composition novel. Note *In re Tuominen*, 213 USPQ 89 (CCPA, 1982); *In re Pearson*, 494 F2d 1399; 181 USPQ 641 (CCPA, 1974); and *In re Hack* 114 USPQ 161. In Claim 1, the passage set forth in the last 2 lines of Claim 1 describes how the composition will be used which is improper in Claims drawn to a product since such language makes the claims alternative. Hence, the language "acts as an osmotic agent

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to maintain a volume ... which otherwise may adhere to each other" should be deleted from Claim 1. This indefinite language in Claim 1 also renders claims dependent from Claim 1 indefinite. See Claims 2, 4-10, 14-18, 21, 22 and 39.

Claims 14-16, which specify the amount of dextrin in the claimed composition, are indefinite since dextrin is the only component set forth in the claimed composition.

6. Applicant's arguments with respect to Claims 1, 2, 4-10, 14-18, 21 and 22 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, and 4-10 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (US Patent No. 5,258,175, already of record).

Applicant claims a composition comprising an aqueous formulation containing a polysaccharide dextrin in an amount effective to reduce adhesions, wherein the dextrin is unsubstituted and contains more than 15% of polymers with a degree of polymerization (DP) greater than 12. Additional limitations in the dependent claims include the aqueous formulation being a solution, specifying the amount of 1,6 linkages in the dextrin, specifying the number average molecular weight and weight average molecular weight of the dextrin, specifying the amount of dextrin present in the composition,

The Davies patent discloses a dextrin used to prepare a dextrin derivative that is derived from a dextrin which is a glucose polymer mixture containing at least 15%, preferably at least 50%, by weight of glucose polymers of D.P. (degree of polymerization) greater than 12. Davies discloses the dextrin as having a weight average molecular weight of from 15,000 to 25,000 (see column 2, paragraphs 1 and 2), which fall within the weight average molecular weight range disclosed in instant Claims

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8 and 9. See column 2, lines 37 and 38 of the Davies patent, wherein starch is hydrolyzed to produce dextrin, which anticipates a dextrin solution. Accordingly, the dextrin composition of the Davies patent anticipates the dextrin composition of the instant claims.

9. Applicant's arguments with respect to Claims 1, 2, 4-10 and 14-16 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

10. Claims 1, 2, 4-10, 14-18, 21, 22 and 39-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Davies (US Patent No. 5,258,175) for the reasons set forth in the previously filed Office Actions.

11. Applicant's arguments filed February 12, 2004 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that the motivation set forth in the Office Action filed February 11, 2003 for combining the Viegas et al patent with the Davies patent was not clear and particular. In response to Applicant's argument the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). A more clearer and particular motivation for combining the references is disclosed hereafter. In column 1, 2nd paragraph, the Davies patent discloses the dextrin being used as an osmotic agent. One would be motivated to combine the Viegas et al patent with the Davies patent since Viegas et al sets forth dextrin compositions that provide a physiologically acceptable vehicle having hypoosmotic, hyperosmotic, or isoosmotic characteristics. Also, Applicants argument that the Viegas et al patent sets forth compositions that are "gelled in situ" is not persuasive since the composition is in solution form prior to contact with the body. Accordingly, the rejection of the claims as

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being unpatentable over the Viegas et al patent in view of the Davies patent is maintained for the reasons of record.

12. Claims 23, 24 and 26-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Milner (US Patent No. 4,886,789) for the reasons set forth in the previously filed Office Actions.

13. Applicant's arguments filed February 12, 2004 have been fully considered but they are not persuasive. Applicant argues against the rejection on the ground that Claim 23 now recites that the dextrin is unsubstituted. This argument is not persuasive since the Viegas et al patent does not disclosed that the polydextrin set forth therein is required to have substituted groups.

Applicant further argues that the combination of the Viegas et al with the Milner patent does not teach or suggest the present invention. The Milner patent, which discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture - which encompassed dextrin, is cited to show that the application of such a polymer to the peritoneal cavity is well known in the art. Accordingly, the rejection of Claims 23, 24 and 26-35 under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al patent in view of the Milner patent is maintained for the reasons of record.

In response to Applicant's argument that the combination of the two references may, at best, provide a film-forming peritoneal dialysis solution, the fact that Applicant has recognized another advantage, which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Accordingly, the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over Viegas et al patent in view of the Milner patent is maintained for the reasons of record.

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Summary

14. All the pending claims are rejected.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

16. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

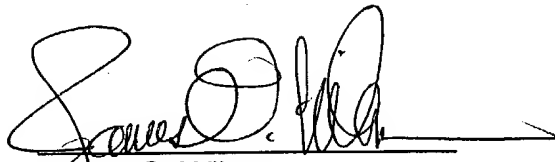
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E. White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600